510(k) Summary of Safety and Effectiveness

(The following information is in conformance with 21 CFR 807.92)

SEP 22 2006

Submitter:

MIMvista Corp.
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Contact Person: Peter Simmelink

Date Summary Prepared: July 27, 2006

Device Name

Trade Name: MIMviewer 1.0
Common Name: Medical Imaging Software
Classification Name: System, Imaging Processing, Radiological

Predicate Devices

K060816	MIM 4.0	MIMvista Corp.

Intended Use

MIMviewer is a software package that aids the physician in the diagnosis of patients by means of medical images. MIMviewer is used to display, register and fuse medical images from multiple modalities.

Device Description

MIMviewer is a software package designed for use in diagnostic imaging which operates on Windows 2000/XP, MacOS X 10.4+ and Linux. MIMviewer is designed to be used as a standalone software package, as a remote viewing client for the MIM (K060816) software package, or as CD-ROM DICOM viewer for referring physicians. MIMviewer provides the physician with the means to display, register and fuse medical images from multiple modalities including PET, SPECT, CT and MRI.

Substantial Equivalence

MIMviewer™ is substantially equivalent to MIM™ 4.0 (NEURO) software (K060816).

Performance Data

MIMvista has conducted performance and functional testing on the MIMviewer software. In all cases, the software passed its' performance requirements and met specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 22 2006

Mr. Peter Simmelink
Chief Operating Officer
MIMvista Corp.
25200 Chagrin Blvd., Suite 200
CLEVELAND OH 44122

Re: K062163
Trade/Device Name: MIMviewer
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 27, 2006
Received: July 28, 2006

Dear Mr. Peter Simmelink:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): ~~TBD~~ K062163

Device Name: MIMviewer

Indications for Use:

The MIMviewer software program is used for the registration, fusion and display of medical ~~images from multi-modalities, such as~~ SPECT, PET, CT, and MRI. MIMviewer provides tools for image review, manipulation, and analysis that assist physicians both inside and outside the medical environment.

Prescription Use X
(Part 21 CFR 801 Subpart D) ~~AND~~/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Legassie

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062163

(Posted November 13, 2003)